UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,787	12/13/2000	Mark A. Ritchart	END-712	6087

7590 08/16/2004

Audley A. Ciamporcero, Jr., Esq.
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER	
FOREMAN, JONATHAN M	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/734,787	Applicant(s) RITCHART ET AL.
	Examiner Jonathan ML Foreman	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-22 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-22 and 35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION*Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 17 – 19 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 2,198,319 to Silverman.

In reference to claims 17 – 19 and 35, Silverman discloses a method including piercing tissue with an instrument comprising an outer hollow cannula (10) and an inner member (14) having a distal end portion disposed within the hollow cannula; positioning the hollow cannula within the tissue at a desired tissue site (Col. 2, lines 4 – 6); actuating a first mechanism (15) associated with the instrument to move the distal end portion of the inner member distally (Col. 2, lines 6 – 9), relative to the outer cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted (Col. 2, lines 9 – 14); actuating a second mechanism (12) associated with the instrument to move the outer hollow cannula distally to retract the distal end portion (Col. 2, lines 14 – 19); and withdrawing the instrument and tissue sample from the tissue (Col. 2, lines 21 – 23). Silverman discloses grasping a tissue sample with a pair of jaws (Figure 5).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,198,319 to Silverman as applied to claim 17 above, and further in view of U.S. Patent No. 4,393,872 to Reznik et al.

In reference to claim 20, Silverman discloses grasping a tissue sample, but fails to disclose using a plurality of hooked extractors. Reznik et al. teaches the use of a plurality of hooked extractors (16) to grasp a tissue sample. It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the grasping members as disclosed by Silverman with the hooked extractors as taught by Reznik et al. to enable the physician to more readily grasp or grip the target tissue (Col. 3, lines 2 – 4).

5. Claim 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 2,198,319 to Silverman as applied to claim 17 above, and further in view of U.S. Patent No. 5,476,101 to Schramm et al.

In reference to claims 21 and 22, Silverman discloses manually actuating the first and second mechanisms. Schramm et al. teaches a biopsy apparatus having a first (55) and second (56) spring element to store energy to drive an inner and outer cannula (Col. 6, lines 9 – 16). It would have been obvious to one having ordinary skill in the art to modify the device as disclosed by Silverman to include a first and second spring element to store energy to drive the outer hollow cannula and the inner member to allow for a more precise automated sampling procedure. Furthermore, the replacement of a manual operation with an automatic operation is a design consideration within the skill of the art. *In re Venner*, 262, F.2d 91, 120 USPQ 192 (CCPA1955).

Response to Arguments

Applicant has asserted that U.S. Patent No. 2,198,319 to Silverman fails to disclose or suggest either a first mechanism or a second mechanism. However, the Examiner disagrees.

Silverman discloses actuating a first mechanism (15) associated with the instrument to move the distal end portion of the inner member distally (Col. 2, lines 6 – 9), relative to the outer cannula, so that the distal end portion expands radially and engages a tissue sample to be extracted (Col. 2, lines 9 – 14); actuating a second mechanism (12) associated with the instrument to move the outer hollow cannula distally to retract the distal end portion (Col. 2, lines 14 – 19). Operating hub (15) and needle hub (12) are considered by the Examiner to be the first and second mechanisms respectively, in that when the operator actuates each respective hub, mechanical energy is then exerted to the outer cannula and inner member. A mechanism need only be "a piece of machinery" (Webster's 10th ed.). A machine is "a constructed thing whether material or immaterial" (Webster's 10th ed.). In the present case, each hub is a piece of machinery. Additionally, Applicant has asserted that the Examiner has not met the burden of providing a prima facie case of obviousness. Applicant has pointed out three basic criteria that must be met: 1. There must be some suggestion or motivation in the prior art to modify a reference or combine reference teachings; 2. There must be a reasonable expectation of success; and 3. The references when combined must teach or suggest all the claim limitations. The Examiner maintains that a prima facie case of obviousness has been met and that hindsight was not the motivation of the combination of references. Claims 21 and 22 were rejected as being unpatentable over U.S. Patent No. 2,198,319 to Silverman in view of U.S. Patent No. 5,476,101 to Schramm et al.; not Schramm et al. in view of Silverman as stated by Applicant. The teaching gained by the disclosure of Schramm et al. is the benefit of using stored energy in a spring element to aid in performing an automated biopsy sampling procedure (Col. 5,lines 53 – 56); not the positioning of the needles. By adding a spring element and associated release mechanisms to the device as disclosed by Silverman, one would reasonably expect to perform a more precise, automated biopsy. Additionally, the court held that broadly providing an automatic or mechanical

means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. *In re Venner*, 262, F.2d 91, 120 USPQ 192 (CCPA1955). Even without the disclosure of Schramm et al., one having ordinary skill in the art would see the benefits of modifying the device as disclosed by Silverman to become an automatic device.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JMLF
August 9, 2004

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700